CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 21-113

MICROBIOLOGY REVIEW(S)

Hecklin

NOV 19 1999

REVIEW FOR HFD-510
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #2 OF NDA 21-113
3 November 1999

A. 1. NDA 21-113 BC
APPLICANT: Bedford Laboratories
300 Northfield Road
Bedford, OH 44146

2. PRODUCT NAMES: Pamidronate Disodium, Injection

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
The product is provided in single-dose 10 mL vials containing 3 mg/mL of the active drug ingredient.

4. METHODS OF STERILIZATION:
The product is terminally sterilized.

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:
The product is indicated for the treatment of moderate or severe hypercalcemia associated with malignancy, with or without bone metastases.

B. 1. DATE OF INITIAL SUBMISSION: 26 February 1999

2. DATE OF AMENDMENT: 21 May 1999 (Subject of this Review)

3. REFERENCE LISTED PRODUCT/MANUFACTURER:
Aredia® - Novartis (see C. REMARKS, below)

4. ASSIGNED FOR REVIEW: 28 October 1999

C. REMARKS: The drug product is compounded, filled, sealed, terminally sterilized, labeled and packaged at Ben Venue Laboratories, Inc., 300 Northfield Road, Bedford, OH.

The cited reference listed product (see B.3., above) is a lyophilized formulation. The reason for citing this product is unclear since this is a New Drug Application rather than a

Generic Application. It may be that the reference drug application (NDA 20-036) contains the clinical data that apply to this application.

This amendment provides for an additional dosage form, which is 9 mg/mL; 10 mL/vial.

D. CONCLUSIONS: The application is recommended for approval on the basis of sterility assurance.

/S/ 3 November 1999
Paul Stinavage, Ph.D.
/S/ 11/19/99

cc: Original NDA 21-113
HFD-510/R. Hedin/S. Markofsky
HFD-805/Consult File/Stinavage

Drafted by: P. Stinavage, 3 November 1999
R/D initialed by P. Cooney

APPEARS THIS WAY
ON ORIGINAL

THIS SECTION WAS DETERMINED **NOT** TO BE RELEASABLE

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APR 1 4 1999

REVIEW FOR HFD-510
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #1 OF NDA 21-113
13 April 1999

A. 1. NDA 21-113
APPLICANT: Bedford Laboratories
300 Northfield Road
Bedford, OH 44146

2. PRODUCT NAMES: Pamidronate Disodium, Injection

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
The product is provided in single-dose 10 mL vials containing 3 mg/mL of the active drug ingredient.

4. METHODS OF STERILIZATION:
The product is terminally sterilized.

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:
The product is indicated for the treatment of moderate or severe hypercalcemia associated with malignancy, with or without bone metastases.

B. 1. DATE OF INITIAL SUBMISSION: 26 February 1999

2. DATE OF AMENDMENT: (none)

3. REFERENCE LISTED PRODUCT/MANUFACTURER:
Aredia® - Novartis (see C. REMARKS, below)

4. ASSIGNED FOR REVIEW: 31 March 1999

C. REMARKS: The drug product is compounded, filled, sealed, terminally sterilized, labeled and packaged at Ben Venue Laboratories, Inc., 300 Northfield Road, Bedford, OH.

The cited reference listed product (see B.3., above) is a lyophilized formulation. The reason for citing this product is unclear since this is a New Drug Application rather than a

Generic Application. It may be that the reference drug application (NDA 20-036) contains the clinical data that apply to this application.

D. CONCLUSIONS: The application is recommended for approval on the basis of sterility assurance.

/S/ 13 Apr 1999
Paul Stinavage, Ph.D.

4/13/99

cc: Original NDA 21-113
HFD-510/R. Hedin/S. Markofsky
HFD-805/Consult File/Stinavage

Drafted by: P. Stinavage, 13 April 1999
R/D initialed by P. Cooney

APPEARS THIS WAY ON ORIGINAL

THIS SECTION WAS DETERMINED **NOT** TO BE RELEASABLE

8 pages

Hedin

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

REQUEST FOR CONSULTATION

(Division/Office) HFD-160 Attn: Peter Cooney			FROM: HFD-510	
DATE March 22, 1999	IND NO.	NDA NO. 21-113	TYPE OF DOCUMENT N	DATE OF DOCUMENT February 26, 1999
NAME OF DRUG pamidronate disodium Inj.		PRIORITY CONSIDERATION S	CLASSIFICATION OF DRUG	DESIRED COMPLETION DATE August 2, 1999
NAME OF FIRM Bedford Laboratories				

REASON FOR REQUEST

I. GENERAL

- ☐ NEW PROTOCOL
- ☐ PROGRESS REPORT
- ☐ NEW CORRESPONDENCE
- ☐ DRUG ADVERTISING
- ☐ ADVERSE REACTION REPORT
- MANUFACTURINGCHANGE/ADDITION
- ☐ MEETING PLANNED BY
- ☐ PRE-NDA MEETING
- ☐ END OF PHASE II MEETING
- ☐ RESUBMISSION
- ☐ SAFETY/EFFICACY
- ☐ PAPER NDA
- ☐ CONTROL SUPPLEMENT
- ☐ RESPONSE TO DEFICIENCY LETTER
- ☐ FINAL PRINTED LABELING
- ☐ LABELING REVISION
- ☐ ORIGINAL NEW CORRESPONDENCE
- ☐ FORMULATIVE REVIEW
- ☐ OTHER *(SPECIFY BELOW)*

II. BIOMETRICS

STATISTICAL EVALUATION BRANCH	STATISTICAL APPLICATION BRANCH
☐ TYPE A OR B NDA REVIEW ☐ END OF PHASE II MEETING ☐ CONTROLLED STUDIES ☐ PROTOCOL REVIEW ☐ OTHER	☐ CHEMISTRY REVIEW ☐ PHARMACOLOGY ☐ BIOPHARMACEUTICS ☐ OTHER

III. BIOPHARMACEUTICS

- ☐ DISSOLUTION
- ☐ BIOAVAILABILTY STUDIES
- ☐ PHASE IV STUDIES
- ☐ DEFICIENCY LETTER RESPONSE
- ☐ PROTOCOL-BIOPHARMACEUTICS
- ☐ IN-VIVO WAIVER REQUEST

IV. DRUG EXPERIENCE

- ☐ PHASE IV SURVEILLANCE/EPIDEMIOLOGY PROTOCOL
- ☐ DRUG USE e.g. POPULATION EXPOSURE, ASSOCIATED DIAGNOSES
- ☐ CASE REPORTS OF SPECIFIC REACTIONS *(List below)*
- ☐ COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP
- ☐ REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY
- ☐ SUMMARY OF ADVERSE EXPERIENCE
- ☐ POISON RISK ANALYSIS

RECEIVED MAR 29 1999 HFD-160

V. SCIENTIFIC INVESTIGATIONS

☐ CLINICAL ☐ PRECLINICAL

COMMENTS/SPECIAL INSTRUCTIONS: Please review the attached microbiology section of a new NDA submitted by Bedford Laboratories.
Dr. Sheldon Markofsky is the reviewing chemist, 827-6383.
Mr. Randy Hedin is the CSO, 827-6382.

cc:

SIGNATURE OF REQUESTER	METHOD OF DELIVERY *(Check one)*
/S/	☒ MAIL ☐ HAND
SIGNATURE OF RECEIVER	SIGNATURE OF DELIVERER
/S/	

3-22-99

Consult.074

TO:

/S/ FW

3/31/99